Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Regulatory Decision Document PRDD2006-02

BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment Containing Hydrogen Peroxide

The technical grade active ingredient hydrogen peroxide and the associated end-use product BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment (containing 27% hydrogen peroxide) for the control of Fusarium tuber rot, bacterial soft rot and silver scurf on potatoes before and during storage are proposed for full registration under the Pest Control Products Regulations.

This Proposed Regulatory Decision Document provides a summary of data received and the rationale for the proposed full registration of these products. The Pest Management Regulatory Agency (PMRA) will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications at the address below.

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Foreword

Health Canada's Pest Management Regulatory Agency (PMRA) has reviewed the submissions for full registration for the technical hydrogen peroxide and the associated end-use product BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment, manufactured by BioSafe Systems Inc., for the control of Fusarium dry rot, bacterial soft rot and silver scurf on potatoes before and during storage.

The PMRA has carried out an assessment of available information in accordance with the Pest Control Products Regulations and has found it sufficient to allow a determination of the safety, merit and value of hydrogen peroxide and the associated end-use product BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment. Hydrogen peroxide has previously been registered by the PMRA for non-food uses; however, this end-use product represents the first food use for this active ingredient. Hydrogen peroxide is an oxidizing agent that is rapidly transformed to water and oxygen. Because the residues in or on stored potatoes are expected to be negligible, no maximum residue level (MRL) is recommended.

The Agency has concluded that the use of hydrogen peroxide and the associated end-use product BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment in accordance with the label has merit and value consistent with the Pest Control Products Regulations and does not entail an unacceptable risk of harm. Therefore, based on the considerations outlined above, the use of hydrogen peroxide and the associated end-use product BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment for the control of Fusarium tuber rot, bacterial soft rot and silver scurf on potatoes before and during storage is proposed for full registration pursuant to the Pest Control Products Regulations.

Table of Contents

1.0 The Active Substance, its Properties and Uses

1.1 Identity of the Active Substance and Impurities

Product Identity: BioSafe—70 Hydrogen Peroxide Technical

Trade name	BioSafe—70 Hydrogen Peroxide Technical
Other names	Hydrogen dioxide Peroxide
Common name	Hydrogen peroxide
International of Union of Pure and Applied Chemistry chemical name	Hydrogen dioxide
Chemical Abstracts Service number	7722-84-1
Structural formula	H-O-O-H
Molecular formula	H_2O_2
Molecular weight	34.01
Identity of relevant impurities of toxicological, environmental and other significance	None of the known impurities has been identified as being of toxicological significance. Technical grade hydrogen peroxide does not form any transformation product that meets Toxic Substances Management Policy (TSMP) Track 1 criteria.

1.2 Physical and Chemical Properties of Active Substances and End-use Product(s)

Technical Product: BioSafe —70 Hydrogen Peroxide Technical

Property	Result	PMRA Comments
Colour	Colourless	
Physical state	Liquid	
Odour	Mildly pungent	
Melting point/range	Liquid	

Property	Result	PMRA Comments
Boiling point/range	**% conc.** **Boiling point (°C)** 10 102 45 108 50 114 70 125 90 141	
Density or specific gravity at 20°C	**% conc.** **Density** 10 1.034 45 1.113 50 1.195 70 1.228 90 1.367	
Water solubility	Miscible	
Solvent solubility	Miscible with many low molecular weight alcohols, glycols and ketones	
Vapour pressure at 25°C	**%** **Vapour Pressure (mm Hg)** 20 1.07 35 1.13 50 1.19 60 1.24	High volatility, will volatilize in the environment
Dissociation constant (pK_a)	8.2	Molecule is neutral at pH < 8.2 and anion at pH > 8.2 in the environment
n-Octanol–water partition coefficient (K_{ow})	0.3	Low potential for bioaccumulation
UV/visible absorption spectrum	Mixtures of H_2O_2 and peracetic acid absorb below 300 nm	Low potential for phototransformation

Property	Result	PMRA Comments
Stability (temperature, metals, sunlight)	Stable in high purity aluminum and 304/316 series stainless steel. Decomposition is highly exothermic and catalyzed by transition metal ion, solid metals or metal oxides, pH 7 or greater, heat, sunlight. H_2O_2 is miscible with many low molecular weight alcohols, glycols and ketones. Concentrated aqueous solutions may become explosive with these solvents.	
Storage stability	Relatively stable in the dark in a clean inert container. Concentrated solutions are more stable. Stabilizers are added.	

End-use Product: BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment

Property	Result
Colour	Colourless
Physical state	Liquid
Odour	Similar to acetic acid
Formulation type	Liquid
Container material and description	10 L holding unit made of high density polyethylene
Specific gravity	1.091
pH	1.05
Oxidizing or reducing action	Strong oxidizer
Storage stability data	Relatively stable in the dark in a clean inert container. Concentrated solutions are more stable. Stabilizers are added.
Miscibility	This product is not to be diluted with petroleum solvents.

1.3 Details of Uses

BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment is a hydrogen peroxide based (27% guarantee) product that is currently registered in the United States for control of fungal and bacterial diseases on field and stored potatoes as well as other vegetables. It is proposed for use in Canada on potato tubers to control fungal and bacterial diseases during storage. Disease claims include Fusarium tuber rot (also known as dry rot), bacterial soft rot and silver scurf. Applications are to be made at the rate of 1:100 (OxiDate/water), applied in two stages. In the first stage, tubers are treated as they enter the storage facility from the bin pilers. Secondly, OxiDate is applied to the tubers as a fine mist or atomized fog, delivered through the waters of humidification. Tubers are to be sprayed daily during the storage period.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Substance as Manufactured

An analytical method based on titration was provided for the determination of the active substance. The method was assessed to be specific, precise and accurate for use as an enforcement analytical method.

2.2 Method for Formulation Analysis

The method presented in Section 2.1 was also used as for analysis of the active substance.

2.3 Methods for Residue Analysis

Crop residue data were not required to support the use of BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment, containing hydrogen peroxide, for use on newly harvested potatoes before storage or as a direct injection into humidification water for postharvest potatoes in storage, as residues of H_2O_2 are expected to be negligible. Therefore, methods for residue analysis of plants, plant products and food of animal origin (data code [DACO] 7.2) were not required. However, the United States Environmental Protection Agency (USEPA) has indicated that they have a method available (not validated) for access by interested parties.

3.0 Impact on Human and Animal Health

3.1 Integrated Toxicological Summary

The registrant submitted waiver requests for all requested toxicity data. The Proposed Regulatory Decision Document PRDD2000-02, *VigorOx™*, and a review of hydrogen peroxide by European Centre for Ecotoxicology of Chemicals (ECETOC 1993) were submitted. The USEPA's Reregistration Eligibility Decision (RED) for peroxy compounds was provided (1993) as well as exemptions from requirement of a tolerance (maximum residue limit) for hydrogen peroxide from the Federal Register of the USEPA from 1998 and 1999 final rules.

The rapid degradation to water and oxygen upon contact with moisture makes absorption, distribution, metabolism and excretion of hydrogen peroxide negligible (PRDD2000-02).

At high doses, hydrogen peroxide is corrosive to the eyes and irritating to the skin and mucous membranes; however, residues are not expected to remain on crops after application of this product. Hydrogen peroxide is highly reactive and short-lived due to instability of the peroxide bond, which leads to rapid degradation and low residues of hydrogen peroxide expected after application.

The available literature indicates that hydrogen peroxide (35%) has slight toxicity by the acute oral route in rats (LD_{50} males 1193 mg/kg), has low dermal acute toxicity in rabbits (LD_{50} >2000 mg/kg), is moderately irritating to the skin and severely irritating or corrosive to the eyes (PRDD2000-02). Hydrogen peroxide is moderately toxic by the inhalation route in mice (LC_{LO} 227 µL/L) (USEPA RED 1993).

ECETOC (1993) reported clinical signs from acute oral exposure to hydrogen peroxide included tremors; decreased motility; prostration; oral, ocular and nasal discharge; reddened lungs; haemorrhagic and white stomachs; and blood-filled intestines. Symptoms after dermal exposure included lacrimation and nasal discharge, while exposure via inhalation resulted in severe pulmonary congestion and emphysema. Mild erythema and moderate to slight edema were observed at 24 hours and severe to moderate erythema and slight to very slight edema were seen at 48 hours after the dermal application of 35% hydrogen peroxide. In preliminary studies at concentrations of 15 and 30% hydrogen peroxide, epidermal necrosis was seen 24 hours after application, with marked epidermal hyperplasia and leukocytic infiltration seen within 6 days of application and the epidermis returning to normal by day 10.

Available literature on human exposure indicates that ingestion will cause irritation of the upper gastrointestinal tract. Decomposition of H_2O_2 results in rapid liberation of oxygen, leading to distension of the esophagus or stomach, and possibly severe damage and internal bleeding. Human exposure by inhalation may result in extreme irritation and inflammation of nose, throat and respiratory tract; pulmonary edema, headache, dizziness, nausea, vomiting, diarrhea, irritability, insomnia, hyper-reflexia; or tremors,

numbness of extremities, convulsions, unconsciousness and shock. Skin contact with hydrogen peroxide liquid will result in temporary whitening of the skin; if the contamination is not removed, erythema and vesicle formation may occur. Exposure to mist or spray may cause stinging and tearing of the eyes. Hydrogen peroxide contact with the eye can cause severe damage such as ulceration of the cornea; sometimes, though rarely, this may appear as long as a week after exposure (International Labour Office 1998).

Hydrogen peroxide is a known mutagen in vitro but is not genotoxic in vivo due to its rapid decomposition to water and oxygen (PRDD2000-02). Although the in vitro genotoxicity data would indicate that a genotoxic mechanism for tumour induction is feasible for hydrogen peroxide, the in vivo data suggest a non-genotoxic mechanism. Because only hydroxyl radicals and singlet oxygen are capable of damaging DNA directly, the genotoxic potential depends on the accessibility of the extremely reactive hydroxyl radical to its target DNA. As the hydroxyl radical and singlet oxygen are short-lived, damage would be local to the area exposed. In vitro, the bacteria or other cells come into direct contact with hydrogen peroxide and genotoxic effects can be induced; in general, the addition of an exogenous metabolic agent or catalase reduces or abolishes the mutagenic response. In vivo, many factors contribute to the reduction of the bioavailability of H_2O_2 for systemic genotoxic action. The occurrence of genotoxic effects on cells that are in direct contact with H_2O_2 (at the site of application) cannot be excluded (ECETOC 1993).

Subchronic exposure of rats to 0.5–1.5% H_2O_2 produced extensive carious lesions and pathological changes in the peridontium, the intensity of the effect varying with the concentration. There was significant inhibition of body-weight gain. Seven out of twenty-four rats administered 1.5% H_2O_2 died during the experiment. A no observed effect level (NOEL) for subchronic administration of hydrogen peroxide to rats was determined to be 0.25% in drinking water based on the limited data that was available (ECETOC 1993).

Subchronic exposure of mice to 0.6% hydrogen peroxide in drinking water caused a depression in water consumption and a decrease in body-weight gain (ECETOC 1993).

A 12-week gavage study (5% solution) showed decreased body-weight gain, hemoglobin concentration, erythrocyte count, blood corpuscular volume, serum aspartate amino-transferase, serum alanine amino-transferase and alkaline phosphatase activity. Organ weight changes were also noted including increased kidney, liver and heart weights and decreased testes and adrenal weights; however, there was no correlating histopathological change.

Rabbits exposed for 6 hours/day, 5 days/week to 22 ppm (31 mg/m^3) of H_2O_2 vapour during a 12-week inhalation study exhibited no change aside from bleaching of hair and some nasal irritation. No change was seen in the eyes following an ophthalmoscopic examination, indicating that vapours did not produce delayed corneal damage. Two dogs exposed to 7 ppm (9.9 mg/m^3) for 6 months exhibited similar results. Hair bleaching and loss were seen after 14 weeks, and sneezing and lacrimation were observed after

23 weeks. There was no significant weight change or alteration in clinical chemistry or hematology. Pathological observation included hyperplasia of the bronchial musculature, collapsed and emphysematous areas in the lungs and thickening of the skin (hair follicles were not destroyed) (ECETOC 1993).

A 13-week drinking water toxicity study of hydrogen peroxide in catalase-deficient mice showed animals that received 3000 ppm had depressed water and food consumption and body weight. At 1000 ppm, females exhibited reduced water consumption with slight effects on food consumption, but not on body weight. Hydrogen peroxide administration did not produce any mortality, clinical sign, hematological effect or organ weight effect on brain, liver, kidneys, adrenals, testes, heart or spleen. Histological findings included mild to minimal duodenal mucosal hyperplasia in animals at 1000 and 3000 ppm. The effects were reversible during a 6-week recovery period. The NOELs determined in this study were 26 and 37 mg/kg bw/day for males and females, respectively (Weiner et al. 2000).

In rats, inhalation exposure to hydrogen peroxide (95 mg/m^3 for 30 exposures over 7 weeks), produced signs of nasal irritation and profuse nasal discharge after 2 weeks as well as lung and tracheal congestion in all animals after 5 to 7 weeks. No significant microscopic change was found in the tissues. A subchronic inhalation study in mice showed similar toxic signs, but there was increased mortality in the mice.

Chronic exposure of mice to 0.15% H_2O_2 in drinking water produced pathological changes in the liver, kidney, gastrointestinal tract and spleen with no effect on body-weight gain (ECETOC 1993).

Chronic exposure of 0.4% hydrogen peroxide in drinking water to mice caused duodenal tumours, but both the International Agency for Research on Cancer (IARC) and the United States Food and Drug Administration concluded there was limited or insufficient evidence of carcinogenicity (PRDD2000-02). When hydrogen peroxide was given to mice at 0.1 and 0.4% in drinking water for up to 740 days, a dose-dependent increased incidence of duodenal hyperplasia was noted in the treated groups (0.1% hydrogen peroxide) compared to controls, and the incidence of duodenal carcinomas was higher in female mice at 0.4% hydrogen peroxide compared to control animals. When 0.4% H_2O_2 was administered for six or seven months to female mice, an increased incidence of duodenal tumours was found in mice with low catalase activity (ECETOC, 1993).

Rabbits and rats administered hydrogen peroxide by gavage for 6 months showed decreased body weight and blood lymphocyte concentrations at the highest dose level (50mg/kg bw/day) and increased haemolysis and number of reticulocytes. Other effects included: decreased hepatic catalase activity; increased hepatic succinyl-dehydrogenase activity; changes in enzyme activity of the stomach, duodenum and cerebrum; and albuminuria. Structural changes were observed in the gastrointestinal mucosa and focal adiposis at autopsy.

Although details are lacking, the studies provided in the ECETOC report tend to show that hydrogen peroxide causes an inflammatory response in the gastro-duodenal tissue of mice. The inflammatory response is more severe in mice with low catalase activity. This inflammatory response may progress into carcinogenic changes in mice. Papillomas were induced in rats, with no malignant tumour of the fore-stomach seen, even at nearly lethal concentration (1–1.5%). Initiation-promotion studies suggest that it is not an initiator in skin, but may be a weak promoter of intestinal tumours in the rat at high concentrations on the skin or nearly lethal concentrations (1.5%) in drinking water.

The literature suggests that the chemistry of dilute hydrogen peroxide and the anatomy/physiology of the gastrointestinal tract make it unlikely that orally ingested hydrogen peroxide would reach the duodenum. It also suggests that lesions in animals receiving H_2O_2 in their drinking water may result from decreased water consumption and ingestion of pelleted dry rodent chow (DeSesso et al. 2000).

The available literature was considered insufficient to allow for an adequate evaluation of reproductive toxicity or teratogenic potential. However, it was concluded that studies to evaluate the reproductive toxicity, teratogenicity or neurotoxicity for hydrogen peroxide were not necessary in view of the rapid decomposition of the active substances to water and oxygen (PRDD2000-02). Hydrogen peroxide and its metabolites are unlikely to accumulate in mammalian organs or tissue long enough to exert significant effects on reproduction and development or induce neurotoxicity.

3.2 Determination of Acceptable Daily Intake

In considering the decomposition of hydrogen peroxide, an acceptable daily intake is not required because negligible risk to human health is expected from the ingestion of potatoes treated with hydrogen peroxide (PRDD2000-02). Hydrogen peroxide is used in a wide range of areas, including sanitizing solutions, food processing (sterilization and bleaching), medicines (dermal disinfectant and mouthwash) and cosmetics.

The USEPA has granted an exemption from the requirement of a tolerance for residues of H_2O_2 in or on all food commodities with an application rate of less than or equal to 1% hydrogen peroxide per application on growing and postharvest crops (USEPA 1999). This is because hydrogen peroxide degrades into water and oxygen. Decomposition is catalysed by the enzymes catalase and glutathione peroxidase, transition and solid metals, as well as heat and sunlight.

The IARC considers that there is limited evidence in experimental animals for carcinogenicity and considers that hydrogen peroxide is not classifiable regarding its carcinogenicity to humans (Group 3).

3.3 Acute Reference Dose

An acute reference dose was not established; hydrogen peroxide was considered unlikely to present an acute hazard from a dietary perspective because hydrogen peroxide degrades immediately to oxygen and water. The available literature suggests that there is no significant treatment-related effect to indicate a concern for acute dietary risk assessment.

3.4 Toxicological Endpoint Selection for Occupational Risk Assessment

Acute toxicology endpoints are considered most appropriate for the occupational risk assessment for the following reasons:

- hydrogen peroxide is highly reactive and subject to rapid decomposition to water and oxygen upon contact with moisture;
- occupational exposure is expected to be intermittent; and
- this compound is highly corrosive.

The PMRA concurs with the USEPA's assessment that peroxy compounds are corrosive and pose acute risk of severe eye and skin irritation to handlers (USEPA 1993). The corrosive nature alone of these compounds will preclude significant dermal exposure. Further, acute risk from exposure via the inhalation route must also be prevented.

3.5 Impact on Human and Animal Health Arising from Exposure to the Active Substance or to its Impurities

3.5.1 Operator Exposure Assessment

The end-use formulation, BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment, is proposed for use to control storage diseases while potatoes are in storage (Use-site Category 12: Stored Food and Feed). The product would be diluted with water and applied by spray to newly-harvested potatoes as they pass along a conveyor belt towards storage bins or, once in storage bins in storage areas, treated as needed by injection into the humidification water. Low occupational exposure is expected. For potatoes being treated prior to storage, the application equipment is automated. The operator connects the lines to the application equipment and inserts the tubing into the 10 L product container. The system is essentially closed. Product is automatically diluted with water and sprayed on the potatoes as they pass under a hood and along a conveyor belt. Potatoes automatically fill the storage bins.

There is potential for dermal and inhalation exposure while attaching and disconnecting the tubing from the product container, while levelling off the storage bins when full (exposure to the arm) and from errant spray from the hooded conveyor belt. Incidental drips may occur when inserting the tubing from the application equipment into the BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment container or disconnecting the equipment. During the humidification process, air levels of hydrogen

peroxide must be monitored. Test strips indicate the level of product in the atmosphere of the storage areas. Postapplication exposure would take place when the strips are being checked, a couple of times a week for a short period (e.g., ½ hour). Entry to treated storage bins is prohibited until hydrogen peroxide air concentrations are below exposure levels established by occupational health and safety authorities in the jurisdiction.

It is the conclusion of the PMRA that mitigation against acute exposures through labelling is the most appropriate regulatory approach for this active ingredient. Specifically, the label must be modified to specify the following:

- Ensure that hydrogen peroxide air concentrations in the workplace do not exceed the exposure levels established by occupational health and safety authorities in your jurisdiction. If values are unknown or exceed these levels, wear NIOSH-approved respiratory protection.

- Do not enter treated storage bins until hydrogen peroxide air concentrations are below exposure levels established by occupational health and safety authorities in your jurisdiction. If values are unknown or exceed these levels, wear NIOSH-approved respiratory protection.

Together with exposure reduction statements on the draft label (e.g., personal protective equipment and clothing), these measures are considered adequate to protect workers against acute hazards.

3.5.2 Bystanders

Given the proposed use, bystander exposure is not anticipated.

3.5.3 Workers

Given the proposed use, worker exposure is expected to be negligible when used with appropriate personal protection.

4.0 Residues

4.1 Nature of the Residue in Plants

A potato metabolism study is not required as catalase enzymes reported to be found in potatoes were likely to break down hydrogen peroxide to oxygen and water. Therefore, there is no residue of concern.

4.2 Nature of the Residue in Animals

Animal metabolism studies are not required because residues of hydrogen peroxide in or on stored potatoes are expected to be negligible. Therefore, no measurable residue of hydrogen peroxide is expected to transfer into animal matrices (meat and milk) when livestock are exposed to treated potato culls and processed potato waste.

4.3 Crop Field Trials

Supervised crop field trials (DACO 7.4.1) and residue decline studies (DACO 7.4.2) were not required. BioSafe OxiDate, having a low concentration of hydrogen peroxide, reacts on contact with the catalase enzymes in potatoes on which it is sprayed and degrades rapidly to oxygen and water. Therefore, residues in or on stored potatoes are expected to be negligible. Hence, no MRL is recommended for promulgation in Table II Division B.15.002(1) of the *Food and Drugs Act* and Regulations.

4.4 Processed Food/Feed

Processing studies (DACO 7.4.5) were not required as residues of hydrogen peroxide in and on treated potatoes are expected to be negligible.

4.5 Meat/Milk/Poultry/Eggs

Residues of hydrogen peroxide in and on stored potatoes are expected to be negligible; therefore, when livestock are exposed to treated potato culls and processed potato waste, no measurable residue of hydrogen peroxide is expected to transfer into animal matrices (meat and milk).

4.6 Dietary Risk Assessment

The PMRA has not established an acceptable daily intake. It is anticipated that the proposed use of hydrogen peroxide in Canada on stored potatoes will not pose a risk to any segment of the population, including infants, children, adults and seniors, when potatoes are subjected to the normal process of washing, peeling and cooking for human consumption.

5.0 Fate and Behaviour in the Environment

BioSafe OxiDate is an indoor-use oxidizing agent for control of fungal and microbial diseases on potatoes. This use pattern will not result in the release of this product to the environment; therefore, non-target organisms will not be exposed. An environmental assessment was not necessary. The technical grade active ingredient hydrogen peroxide has been previously registered by the PMRA for outdoor use as a bleaching agent in pulp and paper production; a summary of the data reviewed for the end-use product *VigorOx™* is available in Proposed Regulatory Decision Document PRDD2000-02, *VigorOx™*.

6.0 Effects on Non-target Species

Data are not required.

7.0 Efficacy

7.1 Effectiveness

7.1.1 Intended Uses

BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment has been demonstrated to control Fusarium tuber rot (also known as dry rot, caused by *Fusarium solani* and *Fusarium roseum*), bacterial soft rot (caused by *Erwinia carotovora*) and silver scurf (caused by *Rhizoctonia solani*) on stored tubers. BioSafe OxiDate is to be applied to tubers just entering storage, then on a daily basis at the rate of 1:100 (OxiDate/water). The product is delivered to the tubers through the waters of humidification according to the label directions. No adverse effects on the tubers were reported when the product was used in conjunction with a plant growth regulator (i.e., chlorpropham) when the sprout inhibitor was applied according to standard potato storage practices.

7.1.2 Mode of Action

BioSafe OxiDate is a peroxygen formulation, which combines hydrogen dioxide with peroxyacetic acid. The combination of these chemicals allows the hydrogen dioxide to become more active, forming a hydroxyl radical. When this hydroxyl radical comes in contact with a disease organism, it reacts with key enzymes and proteins found in the cell walls, especially those containing sulfhydryl groups. The result is a disruption of cellular respiration and cell death. The oxidizing process leads to the complete breakdown of the OxiDate molecules to produce oxygen, water and other inert elements. It is noted that this reaction occurs immediately on contact with the pathogens found on the surface of the tubers. OxiDate is not a systemic fungicide and will not kill pathogens found deep within the tissues of the tuber.

7.1.3 Crops

BioSafe OxiDate is to be used on potato tubers just entering storage and for those in storage.

7.1.4 Effectiveness Against Pests

7.1.4.1 Description of Pest Problem

Fusarium Dry Rot (*Fusarium solani* and *F. roseum*)
These *Fusarium* organisms are almost universally present in cultivated soils. Entry of the pathogens into the tuber occurs mainly through cuts or bruises (mechanical damage) in the tuber surface, or through wounds created by other organisms. The symptoms of Fusarium dry rot include sunken, wrinkled areas of firm, brown rot that can cover a large portion of the tuber surface. The infection can move deep into the tuber, creating large pockets of decay. Low storage temperatures retard the development of Fusarium dry rot; however, if temperatures increase, the infection can continue to spread.

Bacterial Soft Rot (*Erwinia carotovora* var. *carotovora*)
The causative agent of bacterial soft rot is commonly found living freely in the soil. The bacteria are usually introduced to the tuber during harvest, handling or washing and they enter via lenticels, cracks or any injury. Symptoms begin at the surface of the tuber (usually near an eye) and progress inwards, producing rotted tissues that are wet and cream to tan in colour. Infected tissues are distinctly separated from healthy tissues by a dark brown to black margin. Shallow, necrotic spots on the surface are distinct, caused by the organism's entry through lenticels. In the early stages of decay, there is no odour; however, as secondary organisms invade the infected tissues, a foul smell may develop. The disease develops under favourable conditions (adverse temperatures, mechanical damage and free water on the tuber surface), usually affecting tubers previously invaded by other diseases. Development of soft rot may not be apparent until later on in storage and can pass from tuber to tuber, infecting adjacent healthy potatoes.

Silver Scurf (*Helminthosporium solani*)
Silver scurf is considered a seed-borne disease as it does not manifest itself on the stems or foliage. Newly harvested tubers may appear healthy; however, if they are infected, the disease can be expressed within three to five weeks of storage. An infected tuber can spread spores (conidia) to healthy potatoes when tuber piles are handled or moved for shipping and grading, and released spores may also be spread to other piles via the air circulation system. Sporulation is retarded by cooler storage temperatures, but can still occur at 4°C, and is favoured by high humidity and free water on the tuber surface. The symptoms of silver scurf are mainly cosmetic, including irregular patterns of silvery-metallic discolouration of the periderm that can cover a large portion of the tuber surface. In addition, low tuber weight and shrinkage from water loss can occur. It is a disease that mainly affects the visual quality of the tubers and decreases the value of the crop at market.

7.1.4.2 Efficacy Trials

Two studies were reviewed that tested the efficacy of BioSafe OxiDate for control of Fusarium dry rot, bacterial soft rot and silver scurf. The first study was a long-term (eight-month) trial conducted in 1998 in the United States, which tested OxiDate at the rate of 1:100, applied daily for the entire trial. Disease incidence (DI) on tubers was assessed once every four weeks for the presence of Fusarium dry rot, bacterial soft rot and/or silver scurf. Tubers were not inoculated in this experiment; however, adequate disease pressures were evident. By month eight, disease pressures in the untreated check treatment reached 12% DI for silver scurf (peaking at 20% in month three), 20% for soft rot and 15% for Fusarium dry rot. Results suggest that by the end of the eight-month assessment period, OxiDate controlled the DI of silver scurf by 92.5–100%, soft rot by 64–100% and Fusarium tuber rot by 81–100%. Although the frequency of OxiDate application was greater than what is proposed, this trial was conducted under true storage conditions, using application equipment that would be used under normal operating conditions. This trial demonstrated that good control of Fusarium dry rot, bacterial soft rot and silver scurf was achieved with daily applications of OxiDate at the rate of 1:100.

The second trial was conducted in 2001 in New Brunswick. BioSafe was tested at two rates, 1:50 and 1:100, over a storage period of four months. Percent disease severity (DS), the percentage of surface area covered with disease, was assessed after two weeks of daily applications, then every four weeks. Also assessed were tuber sprouting, glucose content, sucrose content and French fry colour. It is noted that the product was applied according to the proposed label directions, and tubers were inoculated with Fusarium dry rot, soft rot or silver scurf pathogens. Results for each assessment date were presented as means for the two potato varieties (Shepody and Norland). The disease control levels for both BioSafe rates were lower than those found in the first trial.

7.1.4.2.1 Fusarium Dry Rot

On the initial assessment date, there was no difference in % DS for Fusarium dry rot between the two Oxidate rates and the check treatment. Disease pressures in the untreated check steadily increased throughout the storage period, reaching a maximum of 18.6% by the final assessment date. Percentage DS for OxiDate-treated potatoes for both rates demonstrated lower DS values compared to the untreated check on each assessment date (values ranged from 37 to 59% for the 1:50 rate and 18.5 to 33% for the 1:100 rate). When the two Oxidate rates were compared, there was a consistent trend of lower % DS values for the 1:50 rate; however, these differences were not strong. By the final assessment date, Oxidate at the 1:50 rate was assessed at 10.2% DS (45% disease control over the untreated check) and at the 1:100 rate was 12.5% DS (32% disease control over the untreated check). These results demonstrate that BioSafe Oxidate at both rates provided moderate control of Fusarium dry rot on stored potatoes when used according to the product directions.

7.1.4.2.2 Bacterial Soft Rot

The disease pressures for soft rot were very low for the duration of the trial, despite inoculation of the tubers with the pathogen. For the first two assessments, there was no sign of tuber infection in any of the treatments. On the third assessment date, soft rot had appeared in the untreated check and the 1:100 rate treatments, although there was less than 1% DS for each. For the last assessment, DS values had reached 2.68% in the untreated check, 1.74% in the 1:100 treatment and 0.33% in the 1:50 treatment. Again, trends indicated that the 1:50 Oxidate rate provided better disease control levels than the 1:100 rate. The disease pressures in this trial were too low to accurately assess the level of disease control for the two rates, although the 1:50 rate appeared to delay the appearance of the disease more than the 1:100 rate. It is unknown whether similar levels of disease control would be found under conditions of high disease pressures.

7.1.4.2.3 Silver Scurf

On the initial disease assessment date there was a large difference in % DS between the untreated check (8%) and the two Oxidate treatments (16.3% for the 1:50 treatment and 17.6% for the 1:100 treatment). By the second assessment date, these differences were no longer apparent, as the disease had progressed rapidly on the untreated check tubers. By the final assessment date, the untreated check tubers reported 83.6% DS, 75.1% for the 1:100 Oxidate treatment and 67.6% for the 1:50 Oxidate treatment. While both Oxidate rates resulted in lower DS values compared to the untreated check tubers, the differences among the three treatments were modest. For the 1:50 rate, percentage of disease control (relative to the untreated check) ranged between 17 and 25%, while for the 1:100 rate, it was between 0 and 18.9%. Trends indicated that the 1:50 Oxidate rate provided slightly better disease control than the 1:100 rate. In general, BioSafe Oxidate provided low to moderate control of silver scurf for this trial, and both rates would be consistent with levels considered to be “disease suppression”.

7.2 Economics

Not assessed.

7.3 Sustainability

7.3.1 Survey of Alternatives (chemical and non-chemical)

Currently, there are no non-chemical products registered for use against fungal or bacterial diseases of stored potatoes. Cultural practices to reduce disease development during tuber storage include reducing the presence of freestanding water, sanitizing the storage bins prior to tubers entering the facility and monitoring humidity levels of the storage areas.

With regards to chemical products, Table 7.3.1.1 lists the postharvest fungicide/bactericide products registered in Canada for use on potatoes.

Table 7.3.1.1 Postharvest Fungicide/Bactericide Products Registered in Canada for Use on Potatoes Just Entering or In Storage

Active Ingredient	FRAC[1] Fungicide Group	Storage Diseases Controlled
Thiabendazole	1	*Fusarium* spp., *Phoma* spp., *Helminthosporium* spp., *Oospora* spp., *Rhizoctonia* spp.
Mancozeb	M3	Fusarium dry rot

7.3.2 Compatibility with Current Management Practices, Including Integrated Pest Management

BioSafe Oxidate can be integrated into existing pest management practices because the product is delivered to the tubers as they enter the bin piler and through the waters of humidification once they are in storage. No new application equipment is necessary for product delivery. There are limited products available to control diseases in storage facilities, so BioSafe Oxidate would be beneficial to growers. Trials have reported growers' concerns that daily applications of the product through the waters of humidification will result in excess moisture in the storage facilities, which is an environment conducive for fungal and bacterial growth. Without additional efficacy data demonstrating that BioSafe Oxidate can be applied less frequently than once daily and still maintain acceptable disease control, moisture levels within the storage facilities will have to be monitored carefully.

7.3.3 Contribution to Risk Reduction

Currently, few products are registered for postharvest (non-foliar) control of fungal or bacterial pathogens on stored potato tubers. Introducing a new product that could reduce the source of disease inoculum on seed tubers will lead to a reduced the need for fungicides later on, including both tuber seed piece treatments and foliar applications.

7.3.4 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Data were not provided to assess the development of resistance. Since BioSafe Oxidate kills pathogens on contact, then quickly breaks down, it is unlikely to lead to resistance development in pathogen populations. At this time, the Fungicide Resistance Action Committee has not determined the fungicide group that hydrogen peroxide falls into and has not made specific resistance management recommendations.

[1] Fungicide Resistance Action Committee www.frac.info/

7.4 Phytotoxicity to Target Plants

No phytotoxic symptom nor visible product residue was noted on tubers treated with BioSafe Oxidate.

7.5 Observations on Undesirable or Unintentional Side Effects (non-target effects)

The effects of BioSafe Oxidate on tuber sprouting, sucrose levels, glucose levels, French fry colour as well as its interaction with a plant growth regulator (chlorpropham) were assessed. OxiDate was demonstrated to have no inhibiting effects on tuber sprouting. In addition, there was no consistent trend associated with the BioSafe OxiDate rate used although differences between treatments were apparent for the number of sprouts per tuber. While differences among treatments occurred, the reported values for glucose and sucrose content were within acceptable ranges. In addition, tubers treated with the 1:100 OxiDate rate had a slightly lighter French fry colour, which is desirable for the French fry industry. When tested in conjunction with a plant growth regulator, chlorpropham (applied according to accepted storage practices), there were no adverse effects noted on the effectiveness of the sprout inhibitor or interactive effects with BioSafe Oxidate.

One study stated that BioSafe Oxidate had a corrosive effect on metal objects that came in direct contact with it, suggesting a potential for damage to any metal machinery that delivers Oxidate via the waters of humidification or to the metal fasteners commonly found on wooden storage bins that will be subjected to Oxidate. Further studies did not replicate this observation, however.

7.6 Conclusions

The efficacy data presented demonstrated that BioSafe Oxidate will control Fusarium tuber rot, bacterial soft rot and silver scurf on stored tubers if applied on tubers entering storage, and then repeat applications made on a daily basis at the rate of 1:100 (OxiDate:water), applied through the waters of humidification. No adverse effects were reported with regards to tuber sprouting when BioSafe Oxidate was applied in conjunction with the commercial sprout inhibitor chlorpropham.

7.6.1 Summary

Table 7.6.1.1 Supported Label Claims (based on efficacy assessments)

Pest claims	BioSafe Oxidate controls silver scurf, Fusarium dry rot and bacterial soft rot on stored potato tubers.
Product rate	Apply to tubers as they enter the storage facility, followed by daily applications at the dilution rate of 1:100 (OxiDate:water).
Application method	Apply the diluted BioSafe Oxidate to tubers as they enter the storage facility. The product will be delivered to the tubers through the waters of humidification as a fine mist or atomized fog. Apply for at least 20 minutes per day, based on a humidification airflow rate of 0.6 cubic feet per minute (cfm). BioSafe OxiDate test strips should be placed periodically around the tubers to determine if a longer application period is needed.
Resistance management	No specific action is recommended at this time.

8.0 Toxic Substances Management Policy

Active Ingredient

BioSafe Oxidate contains the active ingredient hydrogen peroxide, which is rapidly transformed to water and oxygen; therefore, toxicity, environmental exposure, persistence and bioaccumulation are not of concern. The technical grade active ingredient does not contain any impurity that is known to meet the criteria for Track 1 classification under the TSMP[2]. The formulated product does not contain any formulants that are known to contain TSMP Track 1 substances. On this basis, the PMRA concluded that BioSafe OxiDate does not meet the criteria for Track 1 classification under the TSMP.

9.0 Regulatory Decision

The active ingredient hydrogen peroxide and the end-use product BioSafe OxiDate Bactericide/Fungicide Potato Storage Treatment are proposed for full registration, pursuant to the *Pest Control Products Regulations*, for the postharvest control of Fusarium tuber rot, bacterial soft rot and silver scurf on potatoes, applied as the tubers enter storage and daily thereafter at the rate of 1:100 (OxiDate:water).

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[2] The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics

Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca; or through our website at www.pmra-arla.gc.ca

List of Abbreviations

a.i.	active ingredient
bw	body weight
cfm	cubic foot per minute
DACO	data code
DI	disease incidence
DNA	deoxyribonucleic acid
DS	disease severity
ECETOC	European Centre for Ecotoxicology of Chemicals
IARC	International Agency for Research on Cancer
LD_{50}	median lethal dose
LC_{LO}	lethal concentration, low
m^3	cubic metre
mg	milligram
min.	minute
mm	millimetre
MRL	maximum residue level
NIOSH	National Institute for Occupational Safety and Health
nm	nanometre
NOEL	no observable effect level
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRDD	Proposed Regulatory Decision Document
RED	Reregistration Eligibility Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UV	ultraviolet
µg	microgram
µL	micro litre
USEPA	United States Environmental Protection Agency

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